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SERIAL NUMBER	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.

EXAMINER	
ART UNIT	PAPER NUMBER
	7

DATE MAILED:

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☑ This application has been examined ☐ Responsive to communication filed on _____ ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), 0 days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☑ Notice of References Cited by Examiner, PTO-892.
2. ☑ Notice of Draftsman's Patent Drawing Review, PTO-948.
3. ☑ Notice of Art Cited by Applicant, PTO-1449. (9)
4. ☐ Notice of Informal Patent Application, PTO-152.
5. ☑ Information on How to Effect Drawing Changes, PTO-1474..
6. ☐ _____.

Part II SUMMARY OF ACTION

1. ☑ Claims 16→21, 31→36, 38, 44→58, 69→134 are pending in the application.

   Of the above, claims _____ are withdrawn from consideration.

2. ☑ Claims 1→15, 22→30, 37, 39→43, 59→68 have been cancelled.

3. ☐ Claims _____ are allowed.

4. ☑ Claims 16→21, 31→36, 38, 44→58, 69→134 are rejected.

5. ☐ Claims _____ are objected to.

6. ☐ Claims _____ are subject to restriction or election requirement.

7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.

8. ☐ Formal drawings are required in response to this Office action.

9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).

10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____. has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).

11. ☐ The proposed drawing correction, filed _____, has been ☐ approved; ☐ disapproved (see explanation).

12. ☐ Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. _____; filed on _____.

13. ☐ Since this application apppears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.

14. ☐ Other

EXAMINER'S ACTION

The non-statutory double patenting rejection, whether of the obvious-type or non-obvious-type, is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent. *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Van Ornam*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); and *In re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321 (b) and (c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.78 (d).

Effective January 1, 1994, a registered attorney or agent of record may sign a Terminal Disclaimer. A Terminal Disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 16-21,31-36,38,44-58,69-134 are rejected under the judicially created doctrine of double patenting over claims 1-39 of U. S. Patent No. 5,485,827 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

The subject matter claimed in the instant application is fully

disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows: The common subject matter includes seperate sources of pressurized nitric oxide and oxygen containing gases (fig.7 of '827 patent), gas blender (#51 of '827 and the claimed chamber of claim 30), means for controllably releasing said gases from said sources into said blender (the mechanism for controllably releasing said gas into said chamber as recited in claim 30 of '827), a tube having a lumen in communication with said blender (the claimed lumen in communication with said chamber in claim 30 of '827), an NO analyzer (see chemiluminescence measurements in fig.7 of '827), the NO being diluted with an inert gas (see N2 gas source in fig.7 of '827 and recited in claim 11), a mask configured to route said gas mixture into the respiratory system of a mammal (see mask 118 in fig. 18 of '827 patent), an enclosure suitable for providing an ambient atmosphere from which a patient can inhale wherein said enclousre is a mask or tent (see col.13, line 31 of patent '827), a housing equipped with a flowmeter (see fig.7 of '827).

Furthermore, there is no apparent reason why applicant was prevented from presenting claims corresponding to those of the instant application during prosecution of the application which matured into a patent. *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

Claims 16-21,31-36,38,44-58,69-134 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are replete with references back to "...said mammal..." ; all such references should be amended to read --the mammal-- as they occur in method claims and --a mammal-- or --such a mammal-- in apparatus claims. The reference of "...said human..." in claim 38 should read --the human--.

The phrases "...causing said human to inhale..." and "...causing said mammal to inhale..." (appearing in but not limited to claims 38,44 for example) should read --providing a therapeutically effective amount of nitric oxide to a mammal [human] for inhalation-- The above changes prevent any recitation of a mammal or portion of a mammal as an element in the claimed combination. The claim language "...causing said mammal to inhale..." implies that the mammal is a necessary elememt in the claim rather than an intended subject for operation on by the claimed method.

35 U.S.C. § 101 reads as follows:

> "Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title".

Claims 16-21,31-36,38,44-58,69-134 are rejected under 35 U.S.C. § 101 because the claimed invention lacks patentable

utility.

The claimed invention lacks patentable utility because of a lack of any recited means for preventing a patient from inhaling a toxic oxidized product of nitric oxide, namely nitrogen dioxide. It is a well known fact in the art that the process of oxidation of nitric oxide to nitrogen dioxide can occur in as little as 24 seconds. Claims 16-21,31-36,38,44-58,69-134 recite an analyzer for determining the nitric oxide concentration but there is no recited means for determining the concentration of any of the toxic products of nitric oxide including nitrogen dioxide prior to inhalation by the patient in order to ensure that a patient does not inhale such a toxic amount of toxic products including nitrogen dioxide for example. Claim 16 recites causing a mammal to inhale a therapeutically amount of nitric oxide releasing compound. Claim 16 does not recite the use of the nitrogen dioxide analyzer to determine the concentration of any toxic products including nitrogen dioxide. By way of example, one way of providing such protection for a patient against inhalation of toxic products is shown by claim 1 of '827 patent which provides a mixture of gaseous nitric oxide, immediately prior to inhalation.

Any inquiry concerning this communication should be directed to Aaron J. Lewis at telephone number (703) 308-0716.

Aaron J. Lewis
March 24, 1996

AARON J. LEWIS
EXAMINER
ART UNIT 337